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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,955	06/24/2003	Bruce P. Daggy	C75095C1	1208

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EXAMINER	
STITZEL, DAVID PAUL	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,955	DAGGY ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/24/03*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *06/22/06* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11 are drawn to a composition comprising: a cellulose derivative; a lipase inhibitor; and an edible calcium salt, as classified in class 514, subclass 183.

II. Claim 12 is drawn to a method for the dual treatment of not only adiposity, but also faecal incontinence and steatorrhea, wherein said method comprises administering a tablet to a mammal in need thereof, wherein said tablet comprises: a cellulose derivative; a lipase inhibitor; and an edible calcium salt, as classified in class 424, subclass 439.

III. Claims 23 and 24 are drawn to a process for preparing a tablet, wherein said process comprises: (a) mixing methylcellulose, a lipase inhibitor, and an edible calcium salt, optionally together with a disintegrant, a wetting agent, and/or a coloring agent to form a mixture; (b) preparing granulates by either adding an aqueous PVP solution to the mixture of step (a), or spraying an aqueous PVP solution onto the mixture of step (a); (c) blending a wetting agent, a lubricating agent, a diluent, and a disintegrant to form an extragranular mixture; and (d) compacting the granulates of step (b) with the extragranular mixture of step (c), as classified in class 427, subclass 2.14.

IV. Claims 13-19 are drawn to a composition comprising: a cellulose derivative; a lipase inhibitor; and a swellable diluent/filler, as classified in class 424, subclass 465.

V. Claim 20 is drawn to a method for the dual treatment of not only adiposity, but also faecal incontinence and steatorrhea, wherein said method comprises administering a tablet to a mammal in need thereof, wherein said tablet comprises: a cellulose derivative; a lipase inhibitor; and a swellable diluent/filler, as classified in class 424, subclass 494.

VI. Claims 21 and 22 are drawn to a process for preparing a tablet, wherein said process comprises: (a) blending methylcellulose, a lipase inhibitor, a swellable diluent/filler and a lubricating agent, optionally together with a disintegrant to form an intragranular mixture; (b) preparing granulates by either adding an aqueous PVP solution to the intragranular mixture of step (a), or spraying an aqueous PVP solution onto the intragranular mixture of step (a); (c) blending a wetting agent, a lubricating agent, a diluent, and a disintegrant to form an extragranular mixture; and (d) compacting the granulates of step (b) with the extragranular mixture of step (c), as classified in class 424, subclass 474.

Inventions I and II are related as a product and a method of using said product, respectively. In addition, Inventions IV and V are also related as a product and a method of using said product, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another

method that is materially different from the instantly claimed method of using said product. See MPEP § 806.05(h). In the instant case, the compositions claimed in Inventions I and IV can be used by another method that is materially different from the methods claimed in Inventions II and V. For example, as opposed to a method of using said compositions for the dual treatment of not only adiposity, but also faecal incontinence and steatorrhea, as claimed in Inventions II and V, the compositions claimed in Inventions I and IV may alternatively be used for the treatment of Type II diabetes.

Inventions I and III are related as a product and a method of making said product, respectively. In addition, Inventions IV and VI are also related as a product and a method of making said product, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of making the product as claimed can be used to make a materially different product; or (2) the product as claimed can be made by another method that is materially different from the instantly claimed method of making said product. See MPEP § 806.05(f). In the instant case, the compositions claimed in Inventions I and IV can be made by another method that is materially different from the methods claimed in Inventions III and VI. For example, as opposed to making the compositions as claimed in Inventions III and VI, the compositions claimed in Inventions I and IV may alternatively be made by: (a) mixing together all of the aforementioned respective ingredients, except for said lipase inhibitor and said aqueous PVP solution, to form a mixture of inert granulates; (b) compacting the mixture of inert granulates to form a mixture of compacted inert granulates; (c) spray drying an atomized lipase inhibitor solution onto said mixture of compacted inert granulates located on a rotary bed dryer to form a mixture of compacted active granulates; (d) protectively coating said mixture of

compacted active granulates on a fluidized bed dryer with an aqueous PVP solution to form a mixture of protectively coated, compacted active granulates.

Inventions II and III are unrelated. In addition, Inventions V and VI are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 802.01 and 806.06. In the instant case, the methods claimed in Inventions II and V have functions and effects of treating adiposity, faecal incontinence and steatorrhea, whereas the methods claimed in Inventions III and VI have functions and effects of making products that may be utilized for treating Type II diabetes. As a result, the methods claimed in Inventions II and V have a materially different function and effect from the methods claimed in Inventions III and VI, and are therefore unrelated.

Inventions I and IV are related as products that share a common disclosed utility linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products as claimed encompass embodiments that are NOT required to perform the common disclosed utility; or (2) that the products as claimed encompass embodiments that are NOT required to have the substantial structural feature. In the instant case, the compositions claimed in Inventions I and IV share a common disclosed utility of treating adiposity, faecal incontinence and steatorrhea, wherein said compositions are linked to a substantial structural feature, namely both compositions comprise: a lipase inhibitor (that inhibits gastrointestinal fat digestion, thereby creating an excess concentration of fat within the gastrointestinal tract, which results in undesirable side effects, such as steatorrhea and anal oil leakage of undigested fat); and a cellulose derivative (that absorbs fat, thereby reducing the

undesirable side affects associated with the administration of lipase inhibitors). However, the compositions claimed in Inventions I and IV encompass patentably distinct embodiments that are NOT required to perform the common disclosed utility of treating adiposity, faecal incontinence and steatorrhea. More specifically, the composition claimed in Invention I further comprises an edible calcium salt, which is NOT required for the composition of Invention IV to perform the common disclosed utility. On the other hand, the composition claimed in Invention IV further comprises a swellable diluent/filler, which is NOT required for the composition of Invention I to perform the common disclosed utility. Therefore, although the compositions claimed in Inventions I and IV share a common disclosed utility of treating adiposity, faecal incontinence and steatorrhea, which is linked to a substantial structural feature, namely both compositions comprise a lipase inhibitor and a cellulose derivative, the edible formulation of Invention I and the swellable diluent/filler formulation of Invention II encompass patentably distinct embodiments that are NOT required to perform the common disclosed utility.

Inventions II and V are related as methods that share a common disclosed utility linked to a substantial structural feature. The methods in this relationship are distinct if either or both of the following can be shown: (1) that the methods as claimed encompass embodiments that are NOT required to perform the common disclosed utility; or (2) that the methods as claimed encompass embodiments that are NOT required to have the substantial structural feature. In the instant case, the methods claimed in Inventions II and V share a common disclosed utility of treating adiposity, faecal incontinence and steatorrhea, wherein said method comprises administering a tablet to a mammal in need thereof, wherein said tablet comprises: a lipase inhibitor (that inhibits gastrointestinal fat digestion, thereby creating an excess concentration of

fat within the gastrointestinal tract, which results in undesirable side effects, such as steatorrhea and anal oil leakage of undigested fat); and a cellulose derivative (that absorbs fat, thereby reducing the undesirable side affects associated with the administration of lipase inhibitors). However, the methods claimed in Inventions II and V encompass patentably distinct embodiments that are NOT required to perform the common disclosed utility of treating adiposity, faecal incontinence and steatorrhea. More specifically, the method claimed in Invention II comprises administering a tablet to a mammal in need thereof, wherein said tablet further comprises: an edible calcium salt, which is NOT required for the method of Invention V to perform the common disclosed utility. On the other hand, the method claimed in Invention V comprises administering a tablet to a mammal in need thereof, wherein said tablet further comprises: a swellable diluent/filler, which is NOT required for the method of Invention II to perform the common disclosed utility. Therefore, although the methods claimed in Inventions II and V share a common disclosed utility of treating adiposity, faecal incontinence and steatorrhea, which is linked to a substantial structural feature, namely both compositions comprise a lipase inhibitor and a cellulose derivative, the method of Invention II, which comprises administering an edible formulation, and the method of Invention V, which comprises administering a swellable diluent/filler formulation, encompass patentably distinct embodiments that are NOT required to perform the common disclosed utility.

Inventions III and VI are related as processes that share a common disclosed utility linked to a substantial structural feature. The processes in this relationship are distinct if either or both of the following can be shown: (1) that the processes as claimed encompass embodiments that are NOT required to perform the common disclosed utility; or (2) that the processes as claimed

encompass embodiments that are NOT required to have the substantial structural feature. In the instant case, the processes claimed in Inventions III and VI share a common disclosed utility of preparing a tablet, wherein said process comprises: mixing together a lipase inhibitor and a cellulose derivative. However, the processes claimed in Inventions III and VI encompass patentably distinct embodiments that are NOT required to perform the common disclosed utility of preparing a tablet. More specifically, the process claimed in Invention III comprises a process of preparing a tablet, wherein said process further comprises: mixing an edible calcium salt together with said lipase inhibitor and said cellulose derivative, which is NOT required for the process of Invention VI to perform the common disclosed utility. On the other hand, the process claimed in Invention VI comprises a process of preparing a tablet, wherein said process further comprises: mixing a swellable diluent/filler together with said lipase inhibitor and said cellulose derivative, which is NOT required for the process of Invention III to perform the common disclosed utility. Therefore, although the processes claimed in Inventions III and VI share a common disclosed utility of preparing a tablet, which is linked to a substantial structural feature, namely mixing together a lipase inhibitor and a cellulose derivative, the process of Invention III, which further comprises mixing an edible calcium salt together with said lipase inhibitor and said cellulose derivative, and the process of Invention VI, which further comprises mixing a swellable diluent/filler together with said lipase inhibitor and said cellulose derivative, encompass patentably distinct embodiments that are NOT required to perform the common disclosed utility.

Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the prior art search required for each respective invention would be divergent, thereby causing an undue

search burden. As a result, restriction for examination purposes as indicated is proper. Applicants are therefore required under 35 U.S.C. § 121 to elect a single invention for prosecution on the merits.

Conclusion to Restriction Requirement

The Examiner has required restriction between product, methods of making, and methods of using claims. Where Applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn methods of making and methods of using claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Methods of making and methods of using claims that depend from or otherwise include all the limitations of the patentable product claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined methods of making and methods of using claims will be withdrawn, and the rejoined methods of making and methods of using claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and methods of making and methods of using claims may be maintained. Withdrawn methods of making and methods of using claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86

(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the methods of making and methods of using claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named Inventors is no longer an actual Inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Election & Telephone Interview Summary

Pursuant to a telephone interview held with the attorney of record, namely Ms. Dara L. Dinner, Esq., on Thursday, June 22, 2006, a provisional election was made to prosecute the invention of Group IV encompassing claims 13-19. As a result and pursuant to 37 CFR § 1.142(b), claims 1-12 and 20-24 are withdrawn from further consideration as being directed to a non-elected invention.

Status of Claims

Claims 1-12 and 20-24 are withdrawn from further consideration as being directed to a non-elected invention. As a result, claims 13-19 are currently pending and therefore examined herein on the merits for patentability.

Statutory Double Patenting

A statutory double patenting rejection of the "same invention" type finds its support in the language of 35 U.S.C. § 101, which states in part that "whoever invents or discovers any new and useful process ... or composition of matter ... may obtain ***a*** patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 164 USPQ 619 (CCPA 1970). A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by either canceling or amending the conflicting claims so that they are no longer coextensive in scope. However, the filing of a terminal disclaimer ***cannot*** overcome a double patenting rejection based upon 35 U.S.C. § 101.

Claims 14-17 are rejected under 35 U.S.C. § 101 as claiming the same invention as that of conflicting claims 13-16 of U.S. Patent 6,607,749 (hereinafter the conflicting Daggy '749 patent).

Nonstatutory Double Patenting

A nonstatutory double patenting rejection of the "obviousness-type" is based on a judicially created doctrine grounded in public policy so as to prevent not only the unjustified or improper timewise extension of the "right to exclude" granted by a patent, but also possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904,

160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); and *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned or assigned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. See MPEP § 804. However, this does not mean that one is absolutely precluded from all use of the patent disclosure. See MPEP § 804. For example, the specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Furthermore, ***those portions of the specification which provide support for the patent claims may also be examined and considered*** when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-442, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* stated that one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court in *Vogel* also pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use

as prior art, nor is it applying the patent as a reference under 35 U.S.C. § 103, since only the disclosure of the invention claimed in the patent may be examined."

Claims 13, 18 and 19 of the instant application are rejected under the judicially created doctrine of non-statutory obviousness-type double patenting as being unpatentable over conflicting claims 12, 17 and 18 of U.S. Patent 6,607,749 (hereinafter the conflicting Daggy '749 patent).

More specifically, claims 13, 18 and 19 of the instant application are directed to a pharmaceutical composition for a tablet comprising: at least one water soluble, non-fermentable cellulose derivative [genus]; at least one lipase inhibitor in an amount effective for treating adiposity; and at least one swellable diluent or filler, selected from microcrystalline cellulose, corn starch, or Starch 1500; wherein the diluent is either microcrystalline cellulose (present in a ratio of methylcellulose to microcrystalline cellulose of from about 2.1:1 to about 14:1), or corn starch (present in a ratio of methylcellulose to corn starch of from about 7.5:1 to about 15:1).

Claims 12, 17 and 18 of the conflicting Daggy '749 patent are directed to a pharmaceutical composition for a tablet comprising: at least one water soluble, non-fermentable cellulose derivative, which is a methylcellulose having a viscosity of >1000 centipoise [species]; at least one lipase inhibitor in an amount effective for treating adiposity; and at least one swellable diluent or filler, selected from microcrystalline cellulose, corn starch, or Starch 1500; wherein the diluent is either microcrystalline cellulose (present in a ratio of methylcellulose to microcrystalline cellulose of from about 2.1:1 to about 14:1), or corn starch (present in a ratio of methylcellulose to corn starch of from about 7.5:1 to about 15:1).

At least one water soluble, non-fermentable cellulose derivative, which is a methylcellulose having a viscosity of >1000 centipoise, as claimed in claim 12 of the conflicting Daggy '749 patent, is a species of the genus of at least one water soluble, non-fermentable cellulose derivative, as claimed in claim 13 of the instant application, and as a result claim 12 of the conflicting Daggy '749 patent anticipates claim 13 of the instant application.

As a result, although claims 13, 18 and 19 of the instant application are not identical to claims 12, 17 and 18 of the conflicting Daggy '749 patent, the aforementioned claims are not patentably distinct each from the other because said claims are substantially overlapping in scope as discussed hereinabove.

Conclusion

Claims 14-17 are rejected under 35 U.S.C. § 101 as claiming the same invention as that of conflicting claims 13-16 of U.S. Patent 6,607,749 (hereinafter the conflicting Daggy '749 patent). Claims 13, 18 and 19 of the instant application are rejected under the judicially created doctrine of non-statutory obviousness-type double patenting as being unpatentable over conflicting claims 12, 17 and 18 of U.S. Patent 6,607,749 (hereinafter the conflicting Daggy '749 patent).

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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